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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael G Willits

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SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,903	Applicant(s) WILLITS ET AL.	
	Examiner KEITH O. ROBINSON	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-53 is/are pending in the application.
- 4a) Of the above claim(s) 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 37-43) in the reply filed on April 3, 2009 is acknowledged. The traversal is on the ground(s) that the Examiner has over-simplified the technical feature of the invention and that the true technical feature is the expression of flavonol in the flesh of the tomato plant. This is not found persuasive because the claims cite a method of making a hybrid *Lycopersicon* plant expressing flavonol in the peel and flesh of the fruit and the reference cited by the Examiner, Muir et al (Nature Biotechnology 19: 470-474, 2001) teaches elevated expression in tomato fruit peel. See, for example, page 472, 2nd column, last paragraph. In addition, Muir et al teach that transcripts of *chi* were present at relatively high levels in leaf samples and in green, breaker and turning flesh from pBBC50 transgenic plants. See page 472, 1st column, 1st full paragraph.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 44-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 3, 2009.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Claims 37-43 are under examination.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of making a hybrid *Lycopersicon* plant expressing flavonol in the peel and flesh of the fruit of said plant by crossing a wild *Lycopersicon* species that expresses *CHI* in the peel and that expresses genes of the flavonol biosynthetic pathway in the flesh with a *L. esculentum* plant to produce said hybrid plant and hybrids produced thereof.

Claim 37 recites “genes of the flavonol biosynthetic pathway”; however, it is unclear what constitutes “genes of the flavonol biosynthetic pathway” because the claim does not point out what genes make up the flavonol biosynthetic pathway.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goffreda et al (Theor Appl Genet 78: 210-216, 1989), in view of Muir et al (Nature Biotechnology 19: 470-474, 2001), in view of Peralta et al (American J. Botany 88(10): 1888-1902, 2001), in view of Allard (Interspecific hybridization in plant breeding. *In* Principles of plant breeding, Chapter 34, pp. 434-443, 1960).

The claims read on a method of making a hybrid *Lycopersicon* plant expressing flavonol in the peel and flesh of the fruit of said plant by crossing a wild *Lycopersicon* species that expresses *CHI* in the peel and that expresses genes of the flavonol biosynthetic pathway in the flesh with a *L. esculentum* plant to produce said hybrid plant and hybrids produced thereof.

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The claims read on an interspecific cross between two species of *Lycopersicon* wherein a desirable gene from the wild *Lycopersicon* species is introgressed into the *L. esculentum* to produce a hybrid plant having the desired gene.

The state of the art teaches that interspecific crosses are used to improve tomato plants by introgressing desired genes from wild species of *Lycopersicon* into *L. esculentum*. Allard (Interspecific hybridization in plant breeding. *In* Principles of plant breeding, Chapter 34, pp. 434-443, 1960) teaches, “[i]nterspecific hybridization in the genus *Lycopersicon* is particularly interesting because many different hybrids can be secured, and most of the hybrids that can be made are sufficiently fertile to permit extensive studies of their progeny...[and] [h]ybrids of *L. esculentum* with *L. peruvianum* and the closely related species *L. chilense* hold the greatest promise of contributing useful traits to horticultural varieties of tomatoes”. See page 436, 1st paragraph, under section entitled “Interspecific hybridization of tomatoes” and page 437, last paragraph to page 438, line 1.

Therefore, it would have been obvious to one of ordinary skill in the art to use wild species of *Lycopersicon* in a cross with *L. esculentum* to produce hybrid plants that have a desired trait because Allard teaches that wild species are easily crossed with domesticated tomato and that wild species are used in crosses with domesticated tomato to contribute useful traits.

Goffreda et al teach a method of making a hybrid *Lycopersicon* plant by crossing a wild *Lycopersicon* species with a *L. esculentum* plant. See, for example, page 212, Table 2 where it teaches the cross of *L. esculentum* cv. New Yorker x *L. pennellii* LA716

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and the cross of *L. esculentum* cv. VF Vendor x *L. pennellii* LA716 and the F1 hybrids produced from both crosses. In addition, Goffreda et al teach that hybrid plants produced from such a cross had the resistance gene of the wild *Lycopersicon* species. See, page 212, Table 2 and 2nd column, 1st paragraph of 'Results and discussion'.

Goffreda et al differs from the claimed invention in that Goffreda et al teach a wild *Lycopersicon* species that expresses potato aphid resistance and does not teach a wild *Lycopersicon* species that expresses *CHI* in the peel and that expresses genes of the flavonol biosynthetic pathway in the flesh.

Muir et al teach the importance of *CHI* in the flavonol biosynthetic pathway. See, for example, page 470, 1st column, last paragraph to 2nd column, lines 1-6 where it teaches that chalcone isomerase is an enzyme involved in flavonol biosynthesis and has been used to produce transgenic fruit with an increase in peel flavonols. Thus, the *chi* gene and its importance in the flavonol biosynthetic pathway were known to those of ordinary skill in the art.

Peralta et al teach accessions of wild *Lycopersicon* species, including LA1963, LA2884 and LA1926. See, for example, page 1890, Table 1. Thus, accessions of wild *Lycopersicon* species were known to those of ordinary skill in the art.

Therefore, it would have been obvious to one of ordinary skill in the art that the claimed method is a simple substitution of one known element for another to obtain a predictable result.

It would have been obvious to one of ordinary skill in the art to substitute the wild *Lycopersicon* species that expresses potato aphid resistance in the method of Goffreda

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with a wild *Lycopersicon* species that expresses *CHI* in the peel and that expresses genes of the flavonol biosynthetic pathway in the flesh as claimed in the instant invention. The results of the substitution would have been predictable because Allard teaches that wild species of *Lycopersicon* can be crossed with *L. esculentum* to produce hybrid plants that have a desired trait.

MPEP 2141 (I) teaches, “In KSR, the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,”*Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”*Id.* at ___, 82 USPQ2d at 1395...The Supreme Court further stated that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at ___, 82 USPQ2d at 1396”.

Thus, in the instant case, it would have been obvious to one of ordinary skill in the art that the method of Goffreda et al in producing hybrid tomato plants with potato aphid resistance by crossing a domesticated tomato with a wild species tomato having

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potato aphid resistance could be used to produce hybrid tomato plants to have flavonol in the peel and flesh of the fruit simply by crossing a domesticated tomato with a wild species tomato having *CHI* in the peel and that expresses genes of the flavonol biosynthetic pathway in the flesh.

Conclusion

10. No claims are allowed.

Contact Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson

Examiner

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/David H Kruse/

Primary Examiner, Art Unit 1638